

image

09/996,954

1642

Protest under 37 CFR 1.29(a)

To: Assistant Commissioner for Patents
Washington, D.C. 20231

Name of Applicant: Harlan Waksal: represented by Debra A. Sommerville and
Richard De Lucia, Esq and Kenyon&Kenyon,Jay
Alexander Lawrence at Morrison and Foerster

Application Number: 20030157104 A1
Filing date of Application: November 30, 2001
Publication date of Application: August 31, 2003
Title of Invention: Treatment of refractory human tumors with
epidermal growth factor receptor antagonists
Group Unit: Not Known
Name of Examiner: Jasmine Chambers, Director
Current Status and Location of Application: Not Known
**ATTENTION Office of Technology Center 1600, inventions related to biotechnology
and biochemistry**

The patent application by Harlan Waksal contains specifications and a claim to an invention that I conceived. Therefore, this application is in violation of 35 USC 102(g). This invention which I conceived and related in confidence to Harlan Waksal, his brother Sam Waksal, presently incarcerated, their counsel Tom Gallagher and their patent counsel Debra Somerville of Kenyon & Kenyon is the making and use of small peptide equivalents of the monoclonal described in this application. I conceived of what is now claimed as claim 4. Claim 4 is dependent claim which claims a method wherein the antagonist is a small molecule that binds specifically with EGFR/HER1. See below:

1. A method of inhibiting the growth of refractory tumors that are stimulated by a ligand of epidermal growth factor receptor (EGFR) in human patients, comprising treating the human patients with an effective amount of an EGFR/HER1 antagonist.
4. A method according to claim 1 wherein the antagonist is a small molecule that binds specifically with EGFR/HER1.

The methods to identify and isolate such a small molecule are now published in my recently issued patent that has been in the patent office for 18 years. My application was known to all in the biotech office during this extended period. See US patent 6, 605, 448

Therefore, since inventorship in the US is to the person who conceived of the invention, either this application corrects the inventorship under various aspects of 1.47 to include me or the application and its parent should be denied.

Find attached a Confidentiality Agreement signed between myself and Imclone where the invention I conceived and is now claim 4 of Harlan Waksal's application was described.

I, hereby affirm that the above statements are true and that Kenyon & Kenyon ie Imclone's lawyers and Harlan Waksals lawyer J.Alexander Lawrence at Morrison &

Foerster have been served with copies of the above by e mail, fax and first class mail this Oct. 4, 2003.

I request that you consider this protest.

Sincerely yours,

A handwritten signature in cursive script, reading "D. George Pieczenik". The signature is written in black ink and is positioned above the printed name.

Prof. George Pieczenik

Appendix 1 Confidentiality Agreement

**THIS PAGE IS INSERTED BY OIPE SCANNING
AND IS NOT PART OF THE OFFICIAL RECORD**

Best Available Images

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

BLACK BORDERS

TEXT CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT

BLURRY OR ILLEGIBLE TEXT

SKEWED/SLANTED IMAGES

COLORED PHOTOS HAVE BEEN RENDERED INTO BLACK AND WHITE

VERY DARK BLACK AND WHITE PHOTOS

UNDECIPHERABLE GRAY SCALE DOCUMENTS

**IMAGES ARE THE BEST AVAILABLE
COPY. AS RESCANNING *WILL NOT*
CORRECT IMAGES, PLEASE DO NOT
REPORT THE IMAGES TO THE
PROBLEM IMAGE BOX.**

CONFIDENTIALITY AGREEMENT

Infocore Systems Corporation, having a place of business at 630 West 87th Street, New York, New York 10024 (hereinafter called "Infocore") and Sterling Technology, a division of Sterling at 112 West 80th Street, New York, New York (hereinafter called "Sterling") do hereby declare the presence of that which is contained in a connection with functional genetics to Infocore ("GenSelling") as confidential to the place, its maker, that may be exclusively only as to the disclosure by hardware or software to individual. For the purpose of this license and individual genetic information, the Parties to bind the major elements of the first future agree to disclose and to receive completely from the other on the following terms and conditions:

1. For the purpose hereof, the term "Proprietary Information" shall mean all information, to Infocore that is disclosed to the receiving Party. Proprietary Information shall include but not be limited to: (a) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (b) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (c) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (d) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (e) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (f) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (g) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (h) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (i) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (j) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (k) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (l) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (m) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (n) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (o) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (p) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (q) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (r) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (s) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (t) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (u) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (v) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (w) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (x) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (y) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software; (z) information relating to the design, development, construction, use, operation, maintenance, or repair of any hardware or software.

2. The receiving Party shall hold such level of Proprietary Information as is disclosed by the other Party as confidential for a period of three (3) years from the receipt of such information and shall not use such Proprietary Information in any manner that is not described above. To protect confidential information that the Parties will not disclose Proprietary information to any third Party without the written consent of the disclosing Party, and will take commercially reasonable steps, and in any event not less than the same precautions to prevent the unauthorized disclosure of Proprietary Information to third Parties that it takes to prevent unauthorized disclosure of its own confidential information.

3. The Parties shall use their best efforts to restrict the communication of Proprietary Information to their employees and representatives who need to know to the extent necessary for the purpose hereof.

4. Each authorized employee or representative to whom any Proprietary Information is communicated or given shall be informed that the information is confidential and proprietary and shall agree not to disclose or give the information to others.

5. Each authorized employee or representative to whom any Proprietary Information is communicated or given shall agree not to use any of said information except for the purpose of entering into the discussion contemplated hereunder.

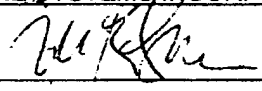
6. Notwithstanding the foregoing, nothing contained in this agreement shall be construed as creating an express or implied license to practice Proprietary Information.

7. This Confidentiality Agreement shall be interpreted in accordance with the laws of the State of New York, without regard to its choice-of-law principles.

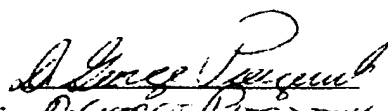
8. This Agreement is intended by the Parties hereto as the final expression of their understanding and is the complete and exclusive statement of the terms hereof notwithstanding any oral representations or statements to the contrary heretofore made. This Agreement contains all of the representations and understandings between the Parties hereto. No modifications of this Agreement or waiver of the terms and conditions hereof shall be binding upon either Party unless approved in writing by an authorized representative of both Parties or shall be effected by the acknowledgment of acceptance of any forms containing other or different terms and conditions whether or not signed by an authorized representative of one of the Parties. No modification or release shall be effective unless in writing signed by the Parties.

IN WITNESS WHEREOF, the Parties hereto have caused this instrument to be executed by their duly authorized officers.

IMCLONE SYSTEMS INCORPORATED

By: 
Print: John B. Landes
Title: Senior Vice President
General Counsel
Date: 2/1/01

GEORGE PIECZENIK

By: 
Print: GEORGE PIECZENIK
Title: _____
Date: 2/1/01